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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/612,783

07/02/2003

Thomas J. La Rosa

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27161 7590 10/30/2008

MONSANTO COMPANY
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EXAMINER

BUI, PHUONG T

ART UNIT

PAPER NUMBER

1638

MAIL DATE

DELIVERY MODE

10/30/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/612,783	Applicant(s) LA ROSA ET AL.	
	Examiner Phuong T. Bui	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4 and 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/14/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Office acknowledges the receipt of Applicant's amendment and Information Disclosure Statement filed July 14, 2008. Claims 1, 2, 4 and 9-13 are pending and are examined in the instant application.

All previous rejections not set forth below have been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is made FINAL.

Since SEQ ID NO:3366 was first disclosed in the instant application, Applicant date of priority benefit is July 2, 2003.

Claim Rejections - 35 USC § 112, second paragraph

2. Claims 4 and 9-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is necessitated by amendment.

In claim 4, "high stringency conditions" is unclear because the specification (p. 11) gives an example of a high stringency condition but does not define this term. It is suggested that Applicant recites the desired hybridization conditions in the claim.

In claims 9-12, "at least" sets a lower limit, and "about" may be more or less than a recited value. Thus, the metes and bounds of "at least about" are unclear.

Clarification and/or correction are required.

Claim Rejections - 35 USC § 101

3. Claims 1, 2, 4 and 9-13 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial, specific asserted utility or a well established utility. This rejection is maintained for reasons of record.

Applicant traverses primarily that SEQ ID NO: 3366 is a member of the cytochrome p450 family, and the sequences in the instant application can be used “for improving nitrogen yield, stress, heat, cold, osmotic, draught, and pest tolerance, increasing seed protein yield and content.”

Applicant's traversals have been carefully considered but are deemed unpersuasive for the following reasons. As Applicant has indicated, P450 family members are extremely diverse and may share only a 16% sequence identity to another member (p. 8 of Remarks of July 14, 2008). Further, cytochrome P450 members have extremely diverse functions, affecting virtually all plant functions. Thus, absent guidance as to how SEQ ID NO:3366 can be used to achieve an immediate and specific benefit, the claimed invention lacks substantial, specific asserted utility. The laundry list of possible utilities for all 12,046 sequences disclosed in the specification does not obviate this rejection because it is unclear which of the above utilities is applicable to SEQ ID NO:3366, and how SEQ ID NO:3366 should be used to achieve its utility. Accordingly, this rejection is maintained.

Claim Rejections - 35 USC § 112, first paragraph

4. Claims 1, 2, 4 and 9-13 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial, specific

asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Further, with regard to claims reciting sequences which hybridizes to SEQ ID NO:3366 and sequences having less than 100% sequence identity to SEQ ID NO:3366, these claims are further not enabled because they encompass unspecified base substitutions, deletions, additions, and/or combinations thereof without any recitation of function.

These rejections are maintained for reasons of record.

Applicant traverses that since the rejection under 35 USC 101 has been overcome, one skilled in the art would know how to make and use the claimed invention. Applicant also traverses primarily that codon degeneracy and conservative amino acid substitutions are known in the art, and “changes to the critical region of a protein should be handled with caution as to avoid influencing the activity of the protein.”

Applicant's traversals have been carefully considered but are deemed unpersuasive for the following reasons. With regard to the first traversal, since the rejection under 35 USC 101 is maintained, the enablement rejection in conjunction with the 101 rejection is maintained. With regard to the second traversal, Applicant's arguments are not commensurate in scope with the claims. The claims are not limited to codon degeneracy changes and conservative amino acid substitutions. Further, neither the specification nor the state of the art at the time the invention was made provides guidance as to where the critical regions(s) are, or what plant function SEQ ID NO:3366 has so that its activity can be maintained. Absent further guidance, one skilled

in the art cannot make and use the claimed invention without undue experimentation. Accordingly, this rejection is maintained.

Remarks

5. No claim is allowed.
6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong T. Bui whose telephone number is 571-272-0793.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571-272-0975. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phuong T. Bui/
Primary Examiner, Art Unit 1638
10/27/08